

REMARKS/ARGUMENTS

This is intended as a full and complete response to the Office Action dated June 25, 2007. Please reconsider the claims pending in the application for reasons discussed below.

DISPOSITION OF CLAIMS

Claims 1-40 are pending in this application. Claim 1 has been amended to include the limitation, "the hydrophobic drug in nanoparticulate form, the oil phase comprising the saturated fatty acid, and the surfactant are combined to form a self-emulsifying drug formulation." Claims 29 and 35 have been amended to include the limitation, "the hydrophobic drug material in nanoparticulate form, the oil phase comprising a saturated C8 through a C12 fatty acid, and the non-ionic surfactant are combined to form a self-emulsifying drug formulation." Support for the limitations included in claims 1, 29, and 35 can be found in the entire detailed description of the invention. Applicants believe that no new matter has been introduced by the amendments presented herein. The amendments have been made in a good faith effort to advance prosecution on the merits.

REJECTIONS UNDER 35 U.S.C. §102

Claims 1, 2, 4-7, 9-14, 18, 22, 23, 25-28, 38, and 39 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,496,811 (Aviv et al.). Reconsideration of this rejection is respectfully requested.

Aviv et al. disclose an oil-in-water emulsion comprising a hydrophobic drug, an oily phase, a surfactant/emulsifier, and an aqueous component, where the mean droplet size of the oil phase is in a range from 0.05 to 0.5 microns. Aviv et al. do not disclose a self-emulsifying formulation comprising a hydrophobic drug in nanoparticulate form. Aviv et al. do not disclose that the mean droplet size is indicative of the particulate size of the hydrophobic drug before formation of the oil-in-water emulsion. Aviv et al. do not disclose the limitation, "wherein the hydrophobic drug in nanoparticulate form, the oil phase comprising the saturated fatty acid, and the surfactant are combined to form a

self-emulsifying drug formulation,” as recited in amended claim 1. This limitation of amended claim 1 is also not found inherently in Aviv et al.

A prior art reference anticipates a claim only if the reference discloses, either expressly or inherently, every limitation of the claim... “[A]bsence from the reference of any claimed element negates anticipation. *Rowe v. Dror*, 112 F.3d 473, 42 USPQ 1550, 1553 (Fed. Cir. 1997). Because Aviv et al. do not disclose expressly or inherently the aforementioned limitation of claim 1, Aviv et al. do not anticipate claim 1. Claims 2, 4-7, 9-14, 18, 22, 23, 25-28, and 38 are also not anticipated by Aviv et al. at least because they depend from claim 1. Claim 39 is also not anticipated by Aviv et al. at least because it includes by reference the limitation, “the hydrophobic drug material in nanoparticulate form, the oil phase comprising a saturated C8 through a C12 fatty acid, and the non-ionic surfactant are combined to form a self-emulsifying drug formulation,” which is not disclosed expressly or inherently by Aviv et al. Withdrawal of the rejection of claims 1, 2, 4-7, 9-14, 18, 22, 23, 25-28, 38, and 39 over Aviv et al. is respectfully requested.

Claims 1, 2, 4-14, 18, 22, 23, 25-28, 38, and 39 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,113,921 (Friedman et al.). Reconsideration of this rejection is respectfully requested.

Friedman et al. disclose a pharmaceutical composition comprising submicron droplets of a water-insoluble drug. Each droplet includes an oily liquid comprising the drug, an emulsifier, and a surfactant. The submicron droplets are formed only after incorporating the drug and surfactant/emulsifier in an oil phase and dispersing the oil phase in an aqueous phase. The examples describe subjecting the oil-in-water emulsion to additional processes to form the submicron droplets. Friedman et al. do not disclose that the water-insoluble drug is in nanoparticulate form prior to forming the oil-in-water emulsion. Friedman et al. do not disclose the limitation, “wherein the hydrophobic drug in nanoparticulate form, the oil phase comprising the saturated fatty acid, and the surfactant are combined to form a self-emulsifying drug formulation,” as recited in amended claim 1. This limitation of amended claim 1 is also not found inherently in Friedman et al.

A prior art reference anticipates a claim only if the reference discloses, either expressly or inherently, every limitation of the claim... "[A]bsence from the reference of any claimed element negates anticipation. *Rowe v. Dror*, 112 F.3d 473, 42 USPQ 1550, 1553 (Fed. Cir. 1997). Because Friedman et al. do not disclose expressly or inherently the aforementioned limitation of claim 1, Friedman et al. do not anticipate claim 1. Claims 2, 4-14, 18, 22, 23, 25-28, and 38 are also not anticipated by Friedman et al. at least because they depend from claim 1. Claim 39 is also not anticipated by Friedman et al. at least because it includes by reference the limitation, "the hydrophobic drug material in nanoparticulate form, the oil phase comprising a saturated C8 through a C12 fatty acid, and the non-ionic surfactant are combined to form a self-emulsifying drug formulation," which is not disclosed expressly or inherently by Friedman et al. Withdrawal of the rejection of claims 1, 2, 4-14, 18, 22, 23, 25-28, 38, and 39 over Friedman et al. is respectfully requested.

Claims 1-6, 9-31, 34-36, and 38-40 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,245,349 (Yiv et al.). Reconsideration of this rejection is respectfully requested.

Yiv et al. disclose a drug formulation including a drug, a phospholipid component, a polypropylene glycol, a high HLB surfactant, and optionally water and/or oil. In concentrate form, the drug formulation does not include water. In diluted form, the drug formulation includes water. The diluted drug formulations are referred to as oil-in-water emulsions. Submicron average particle sizes are reported for the diluted drug formulation but not for the concentrated drug formulation. Yiv et al. do not disclose that the drug is in nanoparticulate form in the concentrated drug formulation. Yiv et al. is non-enabling for nanoparticulate hydrophobic drug in a self-emulsifying suspension. Yiv et al. do not disclose the limitation, "wherein the hydrophobic drug in nanoparticulate form, the oil phase comprising the saturated fatty acid, and the surfactant are combined to form a self-emulsifying drug formulation," as recited in amended claim 1. This limitation of amended claim 1 is also not found inherently in Yiv et al.

A prior art reference anticipates a claim only if the reference discloses, either expressly or inherently, every limitation of the claim... "[A]bsence from the reference of

any claimed element negates anticipation. *Rowe v. Dror*, 112 F.3d 473, 42 USPQ 1550, 1553 (Fed. Cir. 1997). Because Yiv et al. do not disclose expressly or inherently the aforementioned limitation of claim 1, Yiv et al. do not anticipate claim 1. Claims 2-6, 9-28, and 38 are also not anticipated by Yiv et al. at least because they depend from claim 1. Claims 29-31, 34-36, and 39-40 are also not anticipated by Yiv et al. at least because they include by reference the limitation, "the hydrophobic drug material in nanoparticulate form, the oil phase comprising a saturated C8 through a C12 fatty acid, and the non-ionic surfactant are combined to form a self-emulsifying drug formulation," which is not disclosed expressly or inherently by Yiv et al. Withdrawal of the rejection of claims 1-6, 9-31, 34-36, and 38-40 over Friedman et al. is respectfully requested.

CONCLUSION

It is respectfully noted that the Examiner did not reject claims 32, 33, and 37 over any of the cited references nor did the Examiner indicate that these claims are allowable. Applicants respectfully request that the Examiner clarify the status of these claims in the next Office Action. Applicants also reserve the right to present these claims as independent claims, including the limitations of the base and any intervening claims prior to the amendments made in this response.

Applicants believe that this paper is fully responsive to the Office Action dated June 25, 2007, and respectfully request that a timely Notice of Allowance be issued in this case. A call to the undersigned is encouraged if the Examiner believes that a telephone conference would advance prosecution of this application.

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Respectfully submitted,
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